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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/701,536

06/18/2001

Gwong-Jen J. Chang

14114.0332U2

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EXAMINER

PARKIN, JEFFREY S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,536

Applicant(s)

CHANG, GWONG-JEN J.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-54 and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-54 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/12 & 12/02/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Serial No.: 09/701,536
Applicant: Chang, G.-J. J.

Docket No.: 14114.0332U2
Filing Date: 06/18/01

Detailed Office Action

Status of the Claims

Pursuant to the telephonic interview conducted on 05 July, 2005, the finality of the last office action has been withdrawn. Claims 35-54 and 69 are pending in the instant application.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-37, 39-45, 47-49, 51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Phillpotts et al. (1996) in view of Kozak (1987). Phillpotts and colleagues provide isolated nucleic acids comprising a transcriptional unit expressing a flavivirus immunogen (see Abstract, p. 743). The transcriptional unit comprises the St. Louis Encephalitis virus (SLE) prM/E gene (which includes the prM signal sequence). This unit also includes the cytomegalovirus (CMV) major immediate-early (IE) promoter and poly(A) terminator (see second paragraph, p. 744). Compositions comprising the nucleic acid and a pharmaceutically acceptable carrier, as well as, cells comprising the nucleic acids are provided (see third and fourth paragraphs, p. 744). The only limitation of this teaching is that it does not disclose the

utilization of a Kozak consensus sequence to facilitate translation. However, Kozak compared the translational initiation sequences of several hundred higher eukaryotes and ascertained the optimal sequences for translational initiation. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to include a Kozak translational consensus sequence, as taught by Kozak (1987), in the transcriptional unit of Phillpotts *et al.* (1996), since this would facilitate optimum expression of the flavivirus immunogen of interest. Thus, both the motivation and a reasonable expectation of success were present in the prior art.

Claims 38, 46, and 50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Phillpotts *et al.* (1996) in view of Kozak (1987), as set forth *supra* in claims 35-37, 39-45, 47-49, 51, as evidenced by Konishi *et al.* (1992). The aforementioned references do not demonstrate that prM/E expression results in the production of subviral particles comprising both proteins. However, Konishi and colleagues clearly demonstrate that coexpression of the prM/E genes of Japanese encephalitis virus (JEV) results in the production of subviral particles comprising both proteins (see Abstract, p. 714; Results, pp. 716-717). It was also demonstrated that said particles were highly immunogenic. Therefore, one of ordinary skill in the art would have reasonably expected coexpression of the prM/E genes to produce highly immunogenic subviral particles.

Correspondence

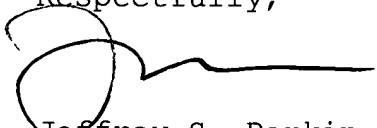
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached

at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

08 June, 2006